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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,725	11/22/2000	William J. Boyle	A-378CIP2C3	5057

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EXAMINER	
DEBERRY, REGINA M	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 01/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/718,725	Applicant(s) BOYLE ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1,2-14, 18, 38 drawn to the isolated OPG nucleic acid, vector, host cell and method of making the polypeptide, classified in class 435, subclass 69.1.

II. Claims 15-17, drawn to the transgenic mammal, classified in class 800, subclass 2.

III. Claims 3,19-37,46-48, drawn to the isolated OPG polypeptide and the pharmaceutical composition, classified in class 530, subclass 350.

IV. Claims 39-41, drawn to the antibody and the method of detecting using the antibody, classified in class 435, subclass 7.1.

V. Claims 42, drawn to a method to assess the ability of binding of OPG with candidate substance, classified in class 435, subclass 7.8.

VI. Claims 43-45, drawn to a method of regulating levels of OPG in an animal with a nucleic acid encoding OPG, classified in class 514, subclass 44.

VII. Claims 49-53, drawn to a method of treating a bone disorder comprising administering OPG polypeptide, classified in class 514, subclass 2.

VIII. Claims 54-60, drawn to osteoprotegerin multimers, classified in class 530, subclass 387.1.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to <u>different</u>

methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups V-VII are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Invention V requires assessing the ability of OPG to bind with a candidate substance, which is not required by any of the other groups. Invention VI requires regulating levels of OPG in an animal with nucleic acid encoding OPG, which is not required by any of the other groups. Invention VII requires treating a bone disorder comprising administering OPG, which is not required by any of the other groups. Therefore, a search and examination of all the methods in one patent application would result in an undue burden, since the searches for these methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions II and III-VIII; III and VI; VIII and V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the transgenic mammal has a different mode of operation from the inventions in Groups III-VIII. The isolated OPG polypeptide has a different mode of operation from the invention in Groups VI. The multimers of Group VIII has a different function from the inventions in Groups V-VII.

Inventions I (product) and V, VI,VII (process of use); III (product) and V, VII (process of use) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated nucleic acid of Group I can be used in a different process such as polymerase chain reactions, the recombinant protein of Group I can be used in processes to make antibodies and the method of treating a bone disorder in Group VII can be practiced with a materially different product. The isolated polypeptide of Group III can be used in processes to make antibodies and the method of treating a bone disorder in Group VII can be practiced with a materially different product.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.06 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I,II, III,,IV,VIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The protein of Groups III and VIII and can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group III and VIII or the transgenic animal in Group II, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Groups III and VIII can be used in materially different methods other than to make the antibody of Group IV, such as in therapeutic or diagnostic methods (e.g., in screening).

The antibody of Group IV can be used to obtain the protein of Groups III,VIII or the recombinantly expressed protein of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. Lastly, the proteins of Groups III and VIII are patentably distinct sequences because they are composed of different amino acid truncations and/or monomers or multimers which impart structural and functional differences.

In addition, the groups recite several patentably distinct sequences (SEQ ID NO:). The sequences are composed of unrelated or diverse sequences, different coding regions and/or impart structural and functional differences. Applicant is required to elect one nucleic acid (SEQ ID NO:) and one amino acid (SEQ ID NO:) sequence it encodes, one beginning point and one end point. This is not a species election but a further election of a group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD
January 3, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER